WSA Master Schedule Template

ID	Task Name	Digest Rate	Reports	Duration	Predecessors	Comments
0	**WSA Template #4-6 month Clinical (Sensory Group Topography Data)**	No	No	840 days?		
1	**Non-Clinical (Acceptability and Reduced Exposure Testing)**	No	No	817 days?		
2	**Acceptability Prep. & Analysis & Testing (Prelim. Product Spec.)**	No	No	377 days		
3	**Material Eval. Request Form (MEVAL) submitted**	Yes	No	0 days		
4	Review Material Eval. Request Form (MEVAL)	No	No	5 days	3	
5	Study Design development	No	No	20 days	4	
6	**Study Design development completed**	Yes	No	0 days	5	
7	Study request approved	No	No	2 days	6	
8	Test Article design approved	No	No	1 day	7	
9	Preparation for production	No	No	20 days	8	May be as long as 6 weeks/30 days
10	Cigarette production	No	No	10 days	9	
11	AMA/PTL testing	No	No	10 days	10	
12	AMA/PTL test results available	No	No	1 day	11	
13	**Test Article release approved**	Yes	No	0 days	12FS+6 days	
14	Request shipment of cigarettes to the lab	No	No	1 day	13	
15	Cigarettes at lab	No	No	20 days	14	
16	**Ship cigarettes to lab completed**	Yes	No	0 days	15	
17	Ames Protocol prep. & review	No	No	97 days	7	
18	Cytotoxicity Protocol prep. & review	No	No	97 days	7	
19	Mouse Lymphoma Protocol prep. & review	No	No	97 days	7	
20	Chemistry Protocol prep. & review	No	No	97 days	7	
21	Metals Protocol prep. & review	No	No	97 days	7	
22	Micronucleus Protocol prep. & review	No	No	97 days	7	
23	Inhalation Protocol prep. & review	No	No	97 days	7	
24	**Acceptability Testing & Reports (Assumes 1 Smoking Condition)**	No	No	253 days		**Assumes 1 smoke condition**
25	**Lab Testing Start**	Yes	No	0 days	16FS+30 days	
26	Ames	No	No	10 days	17	
27	Cytotox	No	No	15 days	18	
28	Mouse Lymphoma	No	No	30 days	19	
29	Chemistry	No	No	50 days	20	
30	Metals	No	No	5 days	21	
31	Micronucleus	No	No	5 days	22	
32	Inhalation (Assumes Recovery & uses a 7-day calendar)	No	No	140 days	23	**Assumes Recovery;Uses 7-day calendar**
33	**Non-Clinical lab testing completed**	Yes	No	0 days	32	
34	Ames draft report rec'd	No	Yes	50 days	26	
35	Ames draft report reviewed	No	Yes	20 days	34	
36	Ames final report	No	Yes	20 days	35	
37	Cytotoxicity draft report rec'd	No	Yes	45 days	27	
38	Cytotoxicity draft report reviewed	No	Yes	20 days	37	
39	Cytotoxicity final report	No	Yes	20 days	38	
40	Mouse Lymphoma draft report rec'd	No	Yes	60 days	28	
41	Mouse Lymphoma draft report reviewed	No	Yes	20 days	40	
42	Mouse Lymphoma final report	No	Yes	20 days	41	
43	Chemistry draft report rec'd	No	Yes	40 days	29	
44	Chemistry draft report reviewed	No	Yes	20 days	43	
45	Chemistry final report	No	Yes	20 days	44	
46	Metals draft report rec'd	No	Yes	80 days	30	
47	Metals draft report reviewed	No	Yes	20 days	46	
48	Metals final report	No	Yes	20 days	47	
49	Micronucleus draft report rec'd	No	Yes	120 days	31	
50	Micronucleus draft report reviewed	No	Yes	20 days	49	
51	Micronucleus final report	No	Yes	20 days	50	
52	Inhalation draft report rec'd	No	Yes	120 days	32	
53	Inhalation draft report reviewed	No	Yes	20 days	52	
54	Inhalation final report	No	Yes	20 days	53	
55	**All draft reports received**	Yes	Yes	0 days	34,37,40,43,46,49,52	
56	**Acceptability Document/Final reports completed**	Yes	No	0 days	36,39,42,45,51,54,48	
57	**Topography data generation (through Sensory Group)**	No	No	20 days		**Topography Data coming from Sensory Group**
58	Subject Recruitment	No	No	10 days	56	
59	Data generation	No	No	10 days	58	
60	**Topography data available**	Yes	No	0 days	59	
61	**Reduced Exposure Prep. & Analysis & Testing (Final Product Spec.)**	No	No	420 days?		
63	**BOM submitted**	Yes	No	0 days	60	
63	BOM review	No	No	1 day?	62	
64	Study Design development	No	No	20 days	63	
65	**Study Design development completed**	Yes	No	0 days	64	

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ID	Task Name	Mgmt Miles	Reports	Duration	Predecessors	Comments
66	Study request approved	No	No	2 days	65	
67	Test Article design approved	No	No	1 day	66	
68	Preparation for production	No	No	20 days	67	May be as long as 6 weeks/30 days
69	Cigarette production	No	No	10 days	68	
70	AMA/PTL testing	No	No	10 days	69	
71	AMA/PTL test results available	No	No	1 day	70	
72	Test Article release approved	Yes	No	0 days	71FS+5 days	
73	Request shipment of cigarettes to the lab	No	No	1 day	72	
74	Ship cigarettes to lab	No	No	20 days	73	
75	Ship cigarettes to lab completed	Yes	No	0 days	74	
76	Ames Protocol prep. & review	No	No	97 days	66	
77	Cytotoxicity Protocol prep. & review	No	No	97 days	66	
78	Mouse Lymphoma Protocol prep. & review	No	No	97 days	66	
79	Chemistry Protocol prep. & review	No	No	97 days	66	
80	Skin Painting (ISO) Protocol prep. & review	No	No	97 days	66	
81	Metals Protocol prep. & review	No	No	97 days	66	
82	Micronucleus Protocol prep. & review	No	No	97 days	66	
83	Inhalation Protocol prep. & review	No	No	97 days	66	
84	**Reduced Exposure Testing & Reports (Assumes 1 Smoking Condition)**	**No**	**No**	**300 days**		**Assumes 1 smoke condition**
85	Lab Testing Start	Yes	No	0 days	75FS+30 days	
86	Ames	No	No	10 days	76	
87	Cytotox	No	No	15 days	77	
88	Mouse Lymphoma	No	No	30 days	78	
89	Chemistry	No	No	50 days	79	
90	Skin Painting (ISO)	No	No	140 days	80	
91	Metals	No	No	5 days	81	
92	Micronucleus	No	No	5 days	82	
93	Inhalation (Assumes Recovery & uses a 7-day calendar)	No	No	140 days	83	**Assumes Recovery;Uses 7-day calendar**
94	Non-Clinical lab testing completed	Yes	No	0 days	93	
95	Ames draft report rec'd	No	Yes	50 days	86	
96	Ames draft report reviewed	No	Yes	20 days	95	
97	Ames final report	No	Yes	20 days	96	
98	Cytotoxicity draft report rec'd	No	Yes	45 days	87	
99	Cytotoxicity draft report reviewed	No	Yes	20 days	98	
100	Cytotoxicity final report	No	Yes	20 days	99	
101	Mouse Lymphoma draft report rec'd	No	Yes	60 days	88	
102	Mouse Lymphoma draft report reviewed	No	Yes	20 days	101	
103	Mouse Lymphoma final report	No	Yes	20 days	102	
104	Chemistry draft report rec'd	No	Yes	40 days	89	
105	Chemistry draft report reviewed	No	Yes	20 days	104	
106	Chemistry final report	No	Yes	20 days	105	
107	Skin Painting draft report rec'd	No	Yes	120 days	90	
108	Skin Painting draft report reviewed	No	Yes	20 days	107	
109	Skin Painting final report	No	Yes	20 days	108	
110	Metals draft report rec'd	No	Yes	80 days	91	
111	Metals draft report reviewed	No	Yes	20 days	110	
112	Metals final report	No	Yes	20 days	111	
113	Micronucleus draft report rec'd	No	Yes	120 days	92	
114	Micronucleus draft report reviewed	No	Yes	20 days	113	
115	Micronucleus final report	No	Yes	20 days	114	
116	Inhalation draft report rec'd	No	Yes	120 days	93	
117	Inhalation draft report reviewed	No	Yes	20 days	116	
118	Inhalation final report	No	Yes	20 days	117	
119	All draft reports received	Yes	Yes	0 days	95,98,101,104,110,113,116	
120	Final reports completed	Yes	Yes	0 days	97,100,103,106,115,118,109,112	
121	**Clinical-Short Term (Study # goes here)**	**No**	**No**	**301 days**		
122	Investigator's Brochure	No	No	30 days	55	
123	Define Study Objectives	No	No	3 days	122SS	
124	Develop Protocol Summary	No	No	15 days	123	
125	Project Plan	No	No	5 days		
126	Development of Project Plan	No	No	5 days	123	
127	Resource Allocation	No	No	0 days	126	
128	Study Budget/Schedule	No	No	0 days	127	
129	CRO Services	No	No	64 days		
130	Clinical Site Selection	No	No	0 days	123	
131	Project Agreement with CRO (Recruitment)	No	No	25 days	130	
132	Purchase Requisition for recruitment	No	No	2 days	131	
133	Project Agreement with CRO (Screening, Study Execution)	No	No	25 days	132	
134	Purchase Requisition for Study Execution	No	No	2 days	133	

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ID	Task Name	Mgmt Milst	Reports	Duration	Predecessors	Comments
135	**Monitoring Services**	No	No	27 days		
136	Monitor Selection	No	No	0 days	124	
137	Project Agreement for Monitoring Services	No	No	25 days	136	
138	Purchase Requisition for Monitoring Services	No	No	2 days	137	
139	Development and Validation of Bioanalytical Methods (if required)	No	No	130 days	123	
140	Questionnaire Development	No	No	30 days	123	
141	**Protocol**	No	No	27 days		
142	Development of Draft Protocol	No	No	15 days	124	
143	Internal Review of Draft Protocol	No	No	10 days	142	
144	Revise Draft Protocol	No	No	2 days	143	
145	**Informed Consent**	No	No	10 days		
146	Development of Informed Consent	No	No	10 days	142SS+5 days	
147	External Review of Draft Protocol and Informed Consent	No	No	15 days	144,145	
148	Revise Draft Protocol and Informed Consent	No	No	5 days	147	
149	Investigators Brochure available	No	No	0 days	148,122	Need for IRB submission.
150	Final Draft Informed Consent, Protocol	No	No	0 days	149	
151	Data analysis plan	No	No	40 days	150	Assumes standardized plan
152	IRB review	No	No	5 days	150	
153	IRB Approval	No	No	0 days	152	
154	Final Informed Consent, Protocol	No	No	0 days	153	
155	Recruitment	No	No	30 days	150,131	
156	Screening	No	No	25 days	153,133,155	
157	Request Test Cigarettes	No	No	0 days	126	
158	Preparation of Test Cigarettes	No	No	65 days	126	Assumes standard timeframe for production
159	Test Cigarettes	No	No	0 days	158	
160	**Clinical Testing**	No	No	6 days		
161	Clinical testing start	Yes	No	0 days	155,159,156	
162	Clinical Testing in Process	No	No	10 edays	161	includes weekends
163	Clinical testing completed	Yes	No	0 days	162	
164	Topography data available	Yes	No	0 days	163FS+20 days	
165	Lab Analysis	No	No	60 days	163	
166	Data Management	No	No	20 days	165	
167	Data Analysis	No	No	20 days	166	
168	Draft Report	No	Yes	20 days	167,166,165	
169	Clinical Evaluation Review of Draft Report	No	No	15 days	168	
170	Draft report results avail. to PM completed	Yes	No	0 days	169	
171	Scientific Data Summary	No	No	20 days	169	
172	Scientific Data Summary completed	Yes	No	0 days	171	
173	Final Report Preparation	No	No	40 days	169	
174	Final report completed	Yes	Yes	0 days	173	
175	**Clinical-Short Term (Menthol)(study # goes here)-(if Needed)**	No	No	301 days		
176	Investigator's Brochure	No	No	30 days	55	8/13/03: Val said that the task can be left in Clinical but Non-Cri
177	Define Study Objectives	No	No	3 days	176SS	
178	Develop Protocol Summary	No	No	15 days	177	
179	**Project Plan**	No	No	5 days		
180	Development of Project Plan	No	No	5 days	177	
181	Resource Allocation	No	No	0 days	180	
182	Study Budget/Schedule	No	No	0 days	181	
183	**CRO Services**	No	No	54 days		
184	Clinical Site Selection	No	No	0 days	177	
185	Project Agreement with CRO (Recruitment)	No	No	25 days	184	
186	Purchase Requisitions for recruitment	No	No	2 days	185	
187	Project Agreement with CRO (Screening, Study Execution)	No	No	25 days	186	
188	Purchase Requisition for Study Execution	No	No	2 days	187	
189	**Monitoring Services**	No	No	27 days		
190	Monitor Selection	No	No	0 days	178	
191	Project Agreement for Monitoring Services	No	No	25 days	190	
192	Purchase Requisition for Monitoring Services	No	No	2 days	191	
193	Development and Validation of Bioanalytical Methods (if required)	No	No	130 days	177	
194	Questionnaire Development	No	No	30 days	177	
195	**Protocol**	No	No	27 days		
196	Development of Draft Protocol	No	No	15 days	178	
197	Internal Review of Draft Protocol	No	No	10 days	196	
198	Revise Draft Protocol	No	No	2 days	197	
199	**Informed Consent**	No	No	7 days		
200	Development of Informed Consent	No	No	7 days	198SS+5 days	
201	External Review of Draft Protocol and Informed Consent	No	No	15 days	198,200	
202	Revise Draft Protocol and Informed Consent	No	No	5 days	201	
203	Investigators Brochure available	No	No	0 days	202	Need for IRB submission.
204	Final Draft Informed Consent, Protocol	No	No	0 days	203	
205	Data analysis plan	No	No	40 days	204	Assumes standardized plan.
206	IRB Review	No	No	5 days	204	
207	IRB Approval	No	No	0 days	206	
208	Final Informed Consent, Protocol	No	No	0 days	207	
209	Recruitment	No	No	30 days	204,185	
210	Screening	No	No	25 days	207,187,209	
211	Request Test Cigarettes	No	No	0 days	182	
212	Preparation of Test Cigarettes	No	No	65 days	211	Assumes standard timeframe for production
213	Test Cigarettes	No	No	0 days	212	
214	**Clinical Testing**	No	No	6 days		

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ID	Task Name	Mgmt Milst	Reports	Duration	Predecessors	Comments
215	Clinical testing start	Yes	No	0 days	209,210,213	
216	Clinical Testing in Process	No	No	10 edays	215	Includes weekends.
217	Clinical testing completed	Yes	No	0 days	216	
218	Topography data available	Yes	No	0 days	217FS+20 days	
219	Lab Analysis	No	No	60 days	217	
220	Data Management	No	No	20 days	219	
221	Data Analysis	No	No	20 days	220	
222	Draft Report	No	Yes	20 days	219,220,221	
223	Clinical Evaluation Review of Draft Report	No	No	15 days	222	
224	Draft report results avail. to PM completed	Yes	No	0 days	223	
225	Scientific Data Summary Preparation	No	No	20 days	223	
226	Scientific Data Summary completed	Yes	No	0 days	225	
227	Final Report Preparation	No	No	40 days	223	
228	Final report completed	Yes	Yes	0 days	227	
229	**Clinical-Long Term (Study # goes here)**	**No**	**No**	**380 days**		Assumes a 6-Month Study
230	Define Study Objectives	No	No	3 days	123	7/8/03: Per Val. Link to Short Term Define Study Obj.
231	Develop Protocol Summary	No	No	15 days	230	
232	**Project Plan**	No	No	5 days		
233	Development of Project Plan	No	No	5 days	230	
234	Resource Allocation	No	No	0 days	233	
235	Study Budget/Schedule	No	No	0 days	234	
236	**CRO Services**	No	No	27 days		
237	Clinical Site Selection	No	No	0 days	230	
238	Project Agreement with CRO (Study Execution)	No	No	25 days	237	Assumes continuation study; no recruitment or screening needs
239	Purchase Requisition for Study Execution	No	No	2 days	238	
240	**Monitoring Services**	No	No	27 days		
241	Monitor Selection	No	No	0 days	231	
242	Project Agreement for Monitoring Services	No	No	25 days	241	
243	Purchase Requisition for Monitoring Services	No	No	2 days	242	
244	Questionnaire Development	No	No	30 days	230	
245	**Protocol**	No	No	27 days		
246	Development of Draft Protocol	No	No	15 days	231	
247	Internal Review of Draft Protocol	No	No	10 days	246	
248	Revise Draft Protocol	No	No	2 days	247	
249	**Informed Consent**	No	No	10 days		
250	Development of Informed Consent	No	No	10 days	246SS+2 days	
251	External Review of Draft Protocol and Informed Consent	No	No	15 days	248,250	
252	Revise Draft Protocol and Informed Consent	No	No	5 days	251	
253	Final Draft Informed Consent, Protocol (and IB)	No	No	0 days	252	
254	Data analysis plan	No	No	40 days	252	Assumes standardized plan.
255	IRB Review	No	No	5 days	253	
256	IRB Approval	No	No	0 days	255	
257	Final Informed Consent, Protocol	No	No	0 days	256	
258	Test Cigarettes	No	No	0 days	159	Assumes product for short & long term studies produced togeth
259	**Clinical Testing**	No	No	83 days		
260	Clinical testing start	Yes	No	0 days	239,258,243	
261	Clinical Testing in Process	No	No	120 edays	260	Assumes 6-mo expos. period; incl weekends.
262	Clinical testing completed	Yes	No	0 days	261	
263	Topography Data Available	No	No	0 days	262FS+20 days	
264	Lab Analysis	No	No	180 days	261SS	
265	Data Management	No	No	20 days	264	
266	Data Analysis	No	No	20 days	265	
267	Draft Report (6-month exposure)	No	No	30 days	266	
268	Draft Report (6-month exposure) completed	No	Yes	0 days	267	
269	Clinical Evaluation Review of Draft Report (6-month exposure)	No	No	20 days	185,268	
270	Draft report results avail. to PM completed	Yes	No	0 days	269	
271	Scientific Data Summary preparation	No	No	20 days	270	
272	Scientific Data Summary completed	Yes	No	0 days	271	
273	Preparation of Final Report (6-month exposure)	No	No	40 days	269	
274	Final report completed	Yes	Yes	0 days	273	
275	**WSA Communications**	**No**	**No**	**772 days**		
276	Product and Method Bibliography	No	No	60 days		Happens about a month before SDS.
277	Scientific Symposium on (if applicable) completed	Yes	No	0 days	170,55	
278	Internal "debate" of proposed claims & supporting science completed	Yes	No	0 days	303SS+5 days	
279	Scientific Q and A completed	Yes	No	0 days	303SS+10 days	
280	Presentation for external audience completed	Yes	No	0 days	279,308,308	
281	Update PREP section of PM science website	No	No	5 days	298,308,310FF,279	
282	Update PREP section of PM science website completed	Yes	No	0 days	281	
283	Claims communication to regulators	No	No	57 days	280,282,310SS	
284	Claims communication to regulators completed	Yes	No	0 days	283	
285	**Surveillance Plan Development and Execution**	**No**	**No**	**210 days**		
286	3rd Party Vendor Contract	No	No	25 days	170,270	
287	3rd Party Vendor Contract completed	Yes	No	0 days	286	
288	Surveillance plan development	No	No	100 days	269FF	finalized by completion of SDS
289	Surveillance plan completed	Yes	No	0 days	288	
290	Surveillance plan execution	No	No	110 days		
291	Questionnaire Constructed	No	No	5 days	269	
292	Finalized (IRB approval)	No	No	10 days	291	
293	Completed	No	No	0 days	292	

WSA Master Schedule Template

ID	Task Name	Mgmt Mile	Reports	Duration	Predecessors	Comments
294	Phase 1: Behavorial Assmt, Exposure Estimation & Complaint Monitoring (start)	Yes	No	0 days	312SS	starts same time as distribution drive/launch
295	**Scientific Data Summary & Final Transfer**	**No**	**No**	**383 days**		
296	Scientific Data Summary Prep (Non-Clinical)	No	No	20 days	55	
297	Scientific Data Summary (Non-Clinical) completed	Yes	No	0 days	296	
298	Scientific Data Summary (Non-Clinical & Clinical)	No	No	10 days	297,171,271,277,276	
299	Scientific Data Summary (Non-Clinical & Clinical) completed	Yes	Yes	0 days	298	
300	Scientific Data Summary (Non-Clinical & Clinical) final internal business review	No	No	10 days	299	
301	Scientific Data Summary (Non-Clinical & Clinical) final internal business review (completed)	Yes	No	0 days	300	
302	**SAB's & External Dates**	**No**	**No**	**120 days**		
303	Scientific Data Summary (Non-clinical & Clinical) sent to SAB Members	Yes	No	0 days	301	4/28/03: new task/milestone added by Ken
304	Scientific Data Summary (Non-clinical & Clinical) review by SAB members	No	No	20 days	303	
305	Scientific Data Summary (Non-clinical & Clinical) review by SAB members (completed)	Yes	No	0 days	304	
306	Presentation to SAB(Proposed)	Yes	No	0 days	304,276	
307	SAB Recommendations	No	No	2 days	306	
308	WSA final recommendations (Includes final business review)	No	No	2 days	306FF+15 days	4/28/03: additional review time added by Ken.
309	WSA final recommendations (Includes final business review) completed	Yes	No	0 days	308	
310	Product announcement to stakeholders (start)	No	No	0 days	309FF+5 days,56	
311	Distribution drive - product available for retail purchase	No	No	20 days	310FS+12 wks	
312	Distribution drive - product available for retail purchase (start)	Yes	No	0 days	311SS	